



JULY 2012

CMS Issues New Regulations for Hospital Conditions of Participation

The Centers for Medicare & Medicaid Services (CMS) issued a final rule that revises the Conditions of Participation (CoP) required for hospitals and critical access hospitals (CAHs) participating in the Medicare and Medicaid programs (the Final Rule) on May 16, 2012. The Final Rule will become effective on July 16, 2012. As noted in the introductory comments to the Final Rule, the intent of the changes to the regulations is to make the hospitals and CAHs more effective, efficient, flexible, and streamlined by eliminating obsolete, duplicative, unnecessary, burdensome, or counterproductive requirements. These amendments are largely, but not wholly, permissive, and hospitals and CAHs are not required to adopt those that are contrary to state law or otherwise would not provide the stated benefits. As a result of the amendments, CMS believes that hospitals and CAHs will have reduced administrative burdens and will be able to achieve greater cost efficiencies. The Final Rule makes substantive changes to nine CoPs and clarifying changes to four other CoPs. Following is a summary of certain substantive changes in the order presented by the regulations and how they address the stated purpose of the amendments.

SINGLE GOVERNING BODY - MULTIHOSPITAL SYSTEMS (42 CFR 482.12)

Previously, each hospital in a multihospital system was required to have its own governing body. The Final Rule allows for the flexibility of a single governing body for the entire system so as to streamline administrative functions and to allow for consistency throughout the system. These changes will allow, but not require, hospitals to streamline governance, thereby reducing redundancy. It is important to note that the Final Rule does not affect or preempt any relevant state corporate or licensing statutes or regulatory requirements that may require each entity to maintain its own governing board.

As written, the Final Rule requires each governing body to include a member, or members, of the hospital's medical staff. CMS explains in the Final Rule that the requirement to include medical staff members on the governing body may increase communication between administrative and medical functions, allowing for the development of more effective and efficient policies; however, significant criticism of this provision followed publication of the Final Rule. The American Hospital Association (AHA) sent a letter to CMS strongly objecting to this revision. Subsequently, on June 15, 2012, in a memorandum to state survey agencies, CMS acknowledged these concerns and said it will hold off on implementing this requirement. CMS

also stated that CMS-approved hospital accreditation programs should not revise standards related to this requirement "until we have addressed the issue completely." CMS noted that it will reconsider this requirement in future rulemaking.

REPORTING OF RESTRAINT-RELATED DEATHS (42 CFR 482.13)

The Final Rule reduces the burden on hospitals and CAHs for reporting patient deaths that occur while the patient is restrained by a 2-point wrist restraint without seclusion, which is commonly used in critical care settings to prevent patients from removing medically necessary devices and equipment. Previously, hospitals and CAHs were required to report all such deaths to CMS via telephone by no later than the next business day. This more stringent reporting requirement still applies to any deaths that occur while a patient is restrained by anything more than a 2-point wrist restraint or that involves seclusion; however, for a death that occurs while the patient is restrained by a 2-point wrist restraint, the hospital or CAH is required to record the information in a log no later than seven days after the patient's death, which will be available to CMS upon its request. As there is no evidence to suggest a cause and effect relationship between the use of 2-point wrist restraints and a patient's death, the new requirements will continue to ensure hospital accountability for patient safety without imposing undue regulatory burden.

MEDICAL STAFF (42 CFR 482.22)

The Final Rule broadens the definition of "medical staff" by allowing hospitals the flexibility to grant privileges to other nonphysician practitioners, such as registered nurses, physician assistants, and pharmacists, within the scope of practice law restrictions under state law. Prior to the amendment, the medical staff could only comprise doctors of medicine or osteopathy and other practitioners. "Other practitioners" was not defined in the regulations and therefore created confusion as to what kinds of practitioners were permitted to be part of the medical staff. With adoption of the Final Rule, it is clear that a medical staff may now include "other categories of nonphysician practitioners" in accordance with the scope of practice laws of the state. CMS states that the intention of the change was to improve patient care through the increased use of an interdisciplinary team. The hospital may determine what categories of nonphysician practitioners are part of the medical staff. In conjunction with expanding the definition of medical staff, the Final Rule has expanded the requirements for examining an applicant's credentials to ensure that all appointments are done in accordance with state law, including scope of practice laws, and medical staff bylaws, rules, and regulations. The Final Rule now also permits a doctor of podiatry to have responsibility for the organization and conduct of the medical staff. Previously, only a doctor of medicine, osteopathy, or dentistry could serve.

CMS also addresses the issue of whether a single and separate medical staff is required for each hospital in a multihospital system. In the proposed regulations, CMS indicated it had considered changes that would expressly allow multihospital systems the option of having a single organized medical staff. This issue had been the topic of debate in the industry, based on earlier comments by CMS. While not specifically addressed in the Final Rule, CMS has clarified and affirmed that it is CMS policy interpretation that each hospital should have its own separate medical staff, even if it is part of a multihospital system. In its letter to CMS, following the publication of the Final Rule, the AHA objected to CMS's position on this issue. The AHA noted that CMS did not include this change in the notice of proposed rulemaking. As such, according to the AHA, the Final Rule violates the Administrative Procedure Act because stakeholders did not have the chance to object when the proposed rule was open for comments. To date, CMS has not responded to this comment.

NURSING SERVICES (42 CFR 482.23)

As with the changes to the medical staff requirements, the changes to the nursing services requirements allow hospitals flexibility to create patient care plans that reflect coordination of care by the various disciplines providing services to patients. The Final Rule permits hospitals using an interdisciplinary plan of care to incorporate the nursing plan into the interdisciplinary plan of care rather than requiring a separate plan as would have otherwise been required. The Final Rule also expands the ability of the nursing staff to prepare and administer drugs and biologicals on the orders of all practitioners, including nonphysician practitioners, who have been granted privileges to write orders by the hospital. It also permits the use of preprinted and electronic standing orders, order sets, and protocols when done in accordance with state laws, the regulations, and hospital policies, provided such policies are based on nationally recognized and evidence-based guidelines. The amendment also eliminates the requirement for authentication of verbal orders within 48-hours but now relies on state law authentication requirements. Another change of note is that patients are now permitted to self-administer hospital-issued and the patient's own medications, provided the hospital has a procedure in place to ensure the patient's care is not negatively affected by such self-administration. CMS hopes that these changes will allow for faster implementation of care for patients while reducing waste and procedural burden.

MEDICAL RECORD SERVICES (42 CFR 482.24)

The changes to the medical records services requirements are consistent with the other changes allowing nonphysician practitioners to write orders in accordance with state laws, including scope-of-practice laws, hospital policies, and medical staff bylaws, rules, and regulations. Again, the intent of such changes is to increase efficiency and interdisciplinary plan of patient care.

INFECTION CONTROL (42 CFR 482.42)

The Final Rule eliminates the requirement for a separate infection control log of incidents related to infections and communicable diseases. The infection control officer is still required to develop a system for identifying, reporting, investigating, and controlling infections and communicable diseases of patients and personnel. The hope is that these changes will eliminate redundancy and will allow hospitals to direct resources where they can better affect patient care.

OUTPATIENT SERVICES (42 CFR 482.54)

The Final Rule creates greater flexibility for hospitals in determining the management structure for outpatient services. Under the Final Rule, hospitals will now be able to appoint more than one individual to be responsible for outpatient services and to make staffing decisions based on the scope and complexity of the outpatient services offered. Prior to the amendment, one individual had to be in charge of outpatient services, and the staffing requirement was not qualified by the scope and complexity of the services offered. These changes will allow hospitals to better utilize their resources and to better align them with the services they offer.

TRANSPLANT CENTER PROCESS REQUIREMENTS - ORGAN RECOVERY AND RECEIPT (42 CFR 482.92)

The Final Rule removes the requirement that a separate blood type and other vial data be verified by the recovery team sent by a transplant center to recover an organ or organs if the

intended recipient is known before organ recovery. These changes do not eliminate the need for the verification of blood type throughout the transplant process, which is required by Organ Procurement Organization's rules. Consequently, the intent of the Final Rule is to eliminate redundancy without affecting patient safety.

CAH PROVISION OF SERVICES (42 CFR 485.602 AND 485.635)

The Final Rule eliminates the term "direct services" and changes it to "patient services," thereby allowing CAHs to provide services through contracts or other arrangements. Although the CAHs will now be able to use nonemployees to provide patient care, which allows them to reallocate costs to other areas, they will still maintain responsibility and oversight for the services. CMS hopes that these changes will allow CAHs to provide greater access to high-quality care for their patients while still managing personnel costs.

SUMMARY

The intent of these amendments in the Final Rule is to allow hospitals and CAHs greater flexibility and control, thereby providing better patient care through better cost allocation and cost savings. They are effective July 16, 2012. Hospitals and CAHs can continue to operate as they have been and still be in compliance with the CoPs, but they now have the option of increasing their use of nonphysician practitioners and streamlining certain administrative functions to increase flexibility in providing patient care, eliminate redundancy, and increase costs savings.

If you have questions about any of these new regulations, please contact a member of Robinson & Cole's [Health Law Group](#).

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